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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,495	06/28/2001	Jay S. Walker	01-025	7185

7590 08/27/2003

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/893,495

Applicant(s)

WALKER ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-45 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-45 and 50-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. In the amendment filed 5/9/03 in paper number 9, the following has occurred: claims 34-37, 39, 42, 44, 45, 50, and 51 have been amended and claims 52 and 53 have been added. Now, claims 34-45, and 50-53 are presented for examination.
2. The rejections under 35 U.S.C. 112 have been withdrawn by the Examiner based on changes made by Applicants to the claims.
3. The rejections under 35 U.S.C. 101 have been withdrawn by the Examiner based on changes made by Applicants to the claims. However, newly added claim 52 contains similar deficiencies as the previously rejected claims and is rejected on the same grounds detailed below.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
5. Claim 52 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
6. The basis of this rejection is set forth in a two-prong test of:
 - (1) whether the invention is within the technological arts; and
 - (2) whether the invention produces a useful, concrete, and tangible result.
7. For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a

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process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

8. In the present case, claim 52 only recites an abstract idea. The recited steps of merely establishing an agreement with an expert and providing compensation to the expert do not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper. These steps only constitute an idea of how to establish and fulfill a business agreement with an expert.

9. Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 52 is deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 52 is rejected under 35 U.S.C. 102(e) as being anticipated by Shults et al., U.S. Patent No. 6,324,516.

12. As per claim 52, Shults teaches a method comprising: teaches establishing an agreement with an expert, wherein the agreement specifies a compensation amount that the

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expert will receive in exchange for providing an agreed upon quantity and nature of medical services (see column 1, lines 51-56 and Figure 1); and causing the compensation amount to be provided to the expert if it is determined that the expert has provided the agreed upon nature and quantity of services (see column 1, lines 63-67 and Figure 1).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 34-41, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud, U.S. Patent No. 5,845,255 in view of Shults et al., U.S. Patent No. 6,324,516 and further in view of Echerer, U.S. Patent No. 6,046,761.

15. As per claim 34, Mayaud teaches a method comprising: transmitting, during a time period, a plurality of requests to an expert, wherein each request comprises a request for a diagnosis of a physiological anomaly associated with a patient (see column 19, lines 17-24); and receiving, from the expert, a response to each of the requests, the response to each request being a diagnosis for the patient of the request (see column 20, lines 20-31). Mayaud do not explicitly teach establishing an agreement with the expert, wherein the agreement specifies a periodic compensation amount that the expert will receive in exchange for providing a minimum number of diagnoses during a time period; and causing the compensation amount to be provided to the expert if, at the end of the time period, it is determined that the expert has provided the minimum amount of diagnoses during the time period. Mayaud also does not explicitly teach sending the requests electronically.

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16. Shults teaches establishing an agreement with an expert, wherein the agreement specifies a compensation amount that the expert will receive in exchange for providing an agreed upon quantity and nature of medical treatments (see column 1, lines 51-56); and causing the compensation amount to be provided to the expert if it is determined that the expert has provided the agreed upon nature and quantity of treatment (see column 1, lines 63-67). It would have been obvious to one of ordinary skill in the art of patient billing at the time of the invention to incorporate the billing and payment scheme of Shults et al. into the system of Mayaud based on the tracking of diagnoses performed by physicians. One of ordinary skill in the art would have been motivated to include such a billing and payment scheme into the system of Mayaud for the purpose of saving money on medical costs by providing negotiating power over medical procedures (see column 3, lines 49-53 of Shults).

17. Echerer teaches electronically sending requests for diagnosis to experts located in remote locations (see column 5, line 67 – column 6, line 4). It would have been obvious to one of ordinary skill in the art of patient diagnosis at the time of the invention to incorporate this electronic request feature into the system of Mayaud. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of eliminating unnecessary “face to face” interaction between patient and doctor and, thereby, reduce costs for both parties (see column 3, lines 13-18 of Echerer).

18. Claim 50 contains substantially similar apparatus limitations to method claim 34 and, as such, is rejected for similar reasons as given above.

19. Claim 51 contains substantially similar method limitations embodied on a computer readable medium to method claim 34 and, as such, is rejected for similar reasons as given above.

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20. As per claim 35, Mayaud in view of Shults et al. teach the method of claim 34 as described above. Mayaud further teaches selecting the expert from a plurality of remote experts based on a received anomaly and an agreement (see column 21, lines 34-41).

21. As per claim 36, Mayaud in view of Shults et al. teach the method of claim 34 as described above. Shults et al. further teach causing a reduced compensation amount to be provided to the expert if at the end of the time period, it is determined that the expert has not provided the minimum amount of service during the time period (see column 1, lines 54-56, it is assumed that ensuring that the agreements have been honored could include providing a reduced payment amount if the agreements are not honored). It would have been obvious to one of ordinary skill in the art of patient billing to incorporate this feature into the invention of Mayaud for the reasons given above with respect to claim 34.

22. As per claim 37, Mayaud in view of Shults et al. teach the method of claim 34 as described above. Shults et al. further teach causing the compensation amount to be withheld from the expert if, at the end of the time period, it is determined that the expert has not provided the minimum amount of service during the time period (see column 1, lines 54-56, it is assumed that ensuring that the agreements have been honored would include withholding payment if the agreements are not honored). It would have been obvious to one of ordinary skill in the art of patient billing to incorporate this feature into the invention of Mayaud for the reasons given above with respect to claim 34.

23. As per claim 38, Mayaud in view of Shults et al. teach the method of claim 34 as described above. Mayaud further teach incrementing a stored number of diagnoses provided by the expert during the time period when the diagnosis is received (see column 42, lines 38-53).

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24. As per claim 39, Mayaud in view of Shults et al. teach the method of claim 38 as described above. Mayaud further teaches determining that the diagnosis provided is associated with at least one factor that indicates a complication in providing the diagnosis (see column 42, lines 38-42); and indicating in the stored diagnoses the at least one factor (see column 42, lines 38-42). In addition, it is assumed that one of ordinary skill in the art would want to give a heavier weight to more complicated diagnoses by flagging. Since the system of Mayaud tracks the number and nature of diagnoses by a particular physician, it is assumed that the more complicated diagnoses could be flagged in the record.

25. As per claim 40, Mayaud in view of Shults et al. teach the method of claim 39 as described above. Mayaud further teaches the at least one factor that indicates a complication in providing the diagnosis comprises at least one of: i) a greater than average complexity in the anomaly, ii) a greater than average amount of time required to provide the diagnosis, iii) an identification that the expert communicated directly with the patient, and iv) an indication that the patient's life was saved due to the diagnosis (see column 42, lines 38-53).

26. As per claim 41, Mayaud in view of Shults et al. teach the method of claim 40 as described above. Mayaud further teaches providing to the expert, at least once during the time period, an indication of a current number of diagnoses provided (see column 42, lines 50-53).

27. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Echerer, U.S. Patent No. 6,046,761 in view of Weinstein, U.S. Patent No. 5,216,596.

28. As per claim 42, Echerer teaches a method, comprising: establishing an agreement with an entity, wherein the entity agrees to continuously monitor physiological parameters through at least one telemetry device in exchange for compensation (see column 2, lines 18-24 and column 3, lines 32-34); wearing the at least one telemetry device (see column 2, lines 2-4);

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receiving an indication from the entity that an anomaly has occurred in at least one of the physiological parameters (see column 3, lines 34-43); and receiving a diagnosis based on the anomaly (see column 4, lines 55-58). Echerer does not explicitly teach that the opinion is based on an opinion of at least one expert contacted by the entity in response to at detection of the anomaly. Weinstein teaches obtaining a second opinion from an expert to aid in diagnosis (see column 5, lines 38-46). It would have been obvious to one of ordinary skill in the art of patient diagnosis at the time of the invention to incorporate the second opinion element of Weinstein into the system of Echerer. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of aiding smaller clinics in diagnosing complex problems (see column 3, lines 12-17 of Weinstein).

29. As per claim 43, Echerer in view of Weinstein teach the method of claim 41 as described above. Echerer further teaches the step of receiving a diagnosis comprises: receiving a diagnosis based on the anomaly, wherein the diagnosis includes at least one instruction regarding an action to be taken in accordance with the diagnosis (see column 6, lines 28-31).

30. As per claim 44, Echerer in view of Weinstein teach the method of claim 43 as described above. Echerer further teaches wherein the action to be taken comprises: an action to be taken by the entity (see column 7, lines 1-5).

31. As per claim 45, Echerer in view of Weinstein teach the method of claim 43 as described above. Echerer further teaches the at least one instruction comprises: an instruction to take a medication (see column 6, lines 28-31).

32. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al., U.S. Patent No. 6,324,516 in view of Echerer, U.S. Patent No. 6,046,761.

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33. As per claim 53, Shults teaches the method of claim 52 as described above. Shults does not explicitly teach the services comprise services for patients who are remote from the expert and whose physiological parameters are being monitored by a remote monitoring system. Echerer teaches providing diagnoses for patients who are remote from an expert (see column 1, lines 40-44) and whose physiological parameters are being monitored by a remote monitoring system (see column 2, lines 2-4). It would have been obvious to one of ordinary skill in the art of patient diagnosis at the time of the invention to incorporate this remote monitoring and diagnosis feature into the system of Shults. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of eliminating unnecessary "face to face" interaction between patient and doctor and, thereby, reduce costs for both parties (see column 3, lines 13-18 of Echerer).

Response to Arguments

34. In the remarks filed 5/9/03 in paper number 9, Applicants argue in substance that (1) the applied rejections under 35 U.S.C. 101 are improper and lack proper statutory or regulatory basis; (2) Echerer does not teach that an expert, other than the doctor monitoring the patient, provides an opinion for diagnosis of the patient; (3) Echerer does not teach "continuously" monitoring one or more physiological parameters of a person; (4) Echerer does not teach "wearing the at least one telemetry device"; (5) Shults does not teach providing a "minimum" quantity of services; (6) Shults does not teach that a doctor must "agree to provide" any medical services; (7) Shults does not teach that a doctor agrees to provide diagnoses (8) Mayaud does not teach "electronically" transmitting requests for diagnosis; (9) Shults does not teach providing "periodic" compensation to the doctor; (10) there is not proper motivation to combine the references as suggested.

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35. In response to Applicants' argument (1), the Examiner notes that the previous rejections, against which Applicants arguments are directed, have been withdrawn by the Examiner based on the addition of the electronic transmission elements in the claims. However, with respect to newly added claim 52, the Examiner has applied a similar rejection detailed above. For statutory support, the Examiner respectfully draws Applicants' attention to court decisions that clearly support the position taken. For example, the court in *In re Toma* stated: " 'technological' or 'useful' arts inquiry must focus on whether claimed subject matter, for example, method of operating machine to translate, is statutory, not on whether product of claimed subject matter, for example, translated text, is statutory, not on whether prior art that claimed subject matter purports to replace, for example, translation by human mind, is statutory, and not on whether claimed subject matter is presently perceived to be improvement over prior art, for example, whether it 'enhances' operation of machine; this was law prior to *Gottschalk v. Benson*, 175 USPQ 673, and was not changed by *Benson*." (emphasis added) 197 USPQ 852, 853 (CCPA 1978). In *In re Musgrave*, 167 USPQ 280 (CCPA 1970), it was held that "... all that is necessary to make a sequence of operational steps a statutory 'process' within 35 U.S.C. 101 is that it be in the technological arts so as to be in consonance with Constitutional purpose to promote progress of 'useful arts' ..." (emphasis added).

36. Applicants' argument (2) is moot in view of the new grounds of rejection detailed above. Additionally, the Examiner respectfully submits that the claims recite that the diagnosis is "based on an opinion of at least one expert". Therefore, according to the claims as currently recited, the entity, with whom the agreement is established, can still provide the diagnosis as long as it is based in some manner on the opinion of another.

37. In response to Applicants' argument (3), the Examiner does not disagree that the patient is only monitored for the duration of the remote encounter with the doctor. However, since the

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claims fail to further define any particular duration for the “continuous” monitoring, this argument is not persuasive. Therefore, the “continuous” monitoring recited in the claims fails to distinguish over the continuous monitoring for the during the remote encounter as taught by Echerer.

38. In response to Applicants’ argument (4), the Examiner respectfully disagrees with Applicants’ interpretation of the teachings of Echerer. For example Echerer teaches that several diagnostic devices must be worn are available to monitor patient health parameters (see column 2, lines 2-4).

39. In response to Applicants’ arguments (5) and (6), the Examiner respectfully disagrees with Applicants’ interpretation of the teachings of Shults. Shults clearly teaches that the UR agreement is an agreement that is negotiated between the payor (i.e. insurance provider) and the provider (i.e. doctor) (see column 1, line 63 – column 2, line 10). In particular, note that, according to this passage, “the provider then treats the patient according to the agreed upon services and then sends the bills to the payor for payment.” (emphasis added). Furthermore, Shults states that UR agreements are “contracts which are negotiated between the provider and the payor” (see column 3, lines 16-17).

40. The Examiner does not disagree with Applicants’ that the “authorized quantity of service” is not explicitly identified by Shults as “minimum”, however, it is respectfully asserted that since both parties (provider and payor) enter into a contract which specifies such a quantity, this amount represents a minimum from the doctor’s perspective. In other words, the doctor is bound by the contract to perform services as specified in order for the payor to be required to pay for such services.

41. In response to Applicants’ argument (7), Shults teaches that the agreement into which the provider and the payor enter specifies a quantity of medical services. The Examiner

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respectfully submits that in the medical arts, "medical services" encompasses both medical treatments as well as medical diagnoses. The Examiner asserts that all embodiments of Shults must be considered. For example, certain medical services (such as treating cancer) may require several intermediate diagnoses to assess a patient's status during treatment. Therefore, while a specific recitation of performing a certain number of diagnoses may not be contained within the four corners of the reference, when taken with the knowledge available to the skilled artisan at the time of the invention, it is submitted that the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

42. Applicants' argument (8) is moot in view of the new grounds of rejection.

43. In response to Applicants' argument (9), as an initial matter, the Examiner respectfully submits that while a "periodic compensation" is specified in the agreement, the claims fail to recite that a doctor is provided with a "periodic compensation". In other words, the doctor is provided with a single compensation amount at the end of a time period if the doctor has provided the minimum number of diagnoses. Moreover, it is assumed that the doctor in Shults repeatedly establishes UR agreements with the payor and, as such, would be compensated periodically when each agreement is completed.

44. In response to Applicants' argument (10), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, not only has proper motivation been provided for each combined reference, the motivation can be found in the applied prior art as

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detailed in the rejections above.

Conclusion

45. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

46. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

49. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

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CLG
8/25/03


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